

**MAIPA Reagents Kit &
MAIPA ELISA Detection Kit**

INTRODUCTION

Neonatal/fetal alloimmune thrombocytopenia (NAIT) due to feto-maternal mismatch for human platelet allo-antigen (HPA) can induce allo-antibodies (anti-HPA) which destroy fetal platelets inducing a severe thrombocytopenia. NAIT has an estimated incidence of 1/1000 pregnancies and *in utero* cerebral bleeds or ventriculomegaly may occur. The screening and identification of allo-antibodies is a mandatory step to prevent and cure these manifestations. Post-Transfusion Purpura (PTP) is another immune mediated destruction of platelets due to anti-HPA allo-antibodies. Platelet Refractoriness (PR) is a clinical situation in which transfused platelets are destroyed by allo-antibodies produced by the recipient. The characterization of these antibodies is a necessary step to provide efficient platelet transfusion.

Monoclonal Antibody-specific Immobilization of Platelet Antigen (MAIPA) is a qualitative technique for platelet antibody detection and/or identification and is considered the gold standard method in the platelet immunology field.

apDia offers all cells, control plasma/serum, reagents and materials necessary to perform the MAIPA procedure. The products are either offered as a complete MAIPA kit or as separate modules allowing to order reagents for defined steps of the MAIPA procedure. If one decides to replace one of the modules by their own reagents, the MAIPA assay should then be validated by themselves using the set of reagents as they will be used.

REAGENT COMPOSITIONS



1. MAIPA Reagents Kit

Ref. 900004

The apDia MAIPA Reagents Kit contains the necessary buffers, monoclonal antibodies and microplate to perform the first part of a MAIPA procedure, i.e. all steps preceding and including the lysis of the cells. The monoclonal antibodies are directed against platelet glycoproteins that carry the most relevant platelet allo-antigens: GpIIb/IIIa, GpIbIX, GpIaIIa and β -2-microglobuline/ HLA.

The kit contains 1 microplate, 1 vial of each monoclonal antibody specificity, one bottle containing 10x concentrated wash solution for washing the cells and one bottle of ready-to-use lysis buffer.

Component	Description	Quantity, Volume	Volume needed per well (test)	Format
Microplate MTP	12 individual strips	1 plate, 96 wells		RTU
Antibody MAB IIbIIIa	Anti-GpIIbIIIa, 10 μ g/ml	2 vials, 1,2 ml	50 μ l	RTU
Antibody MAB Ialla	Anti-GpIaIIa, 10 μ g/ml	1 vial, 1,8 ml	50 μ l	RTU
Antibody MAB IbIX	Anti-GpIbIX, 10 μ g/ml	1 vial, 1,5 ml	50 μ l	RTU
Antibody MAB HLA	Anti-HLA (β 2M), 10 μ g/ml	1 vial, 1,5 ml	50 μ l	RTU
Cell Wash Buffer CELLWASHBUF 10x	MAIPA Platelet Wash Buffer	1 vial 20 ml	(2+2+4) x 200 μ l	10x
Platelet Lysis buffer LYSBUF	MAIPA Platelet Lysis Buffer	1 vial, 15 ml	130 μ l	RTU

2. MAIPA ELISA Detection Kit

Ref. 900005

ELISA kit for analyzing the MAIPA lysate in ELISA configuration.

The kit contains all buffers and reagents allowing ELISA performance to complete the MAIPA protocol.

Component	Description	Quantity, Volume	Volume needed per well (test)	Format
Coated microtiterplate COATMTP	Goat anti-mouse IgG coated microtiterplate	1 plate, 96 wells		RTU
Conjugate CONJ	Goat anti-Human IgG-HRP	1 vial, 12 ml	100 µl	RTU
ELISA Wash buffer ELISAWASHBUF 20x	TRIS buffered Triton X-100 / Tween 20	1 vial, 50 ml	12 x 200 µl	20x
Chromogen TMB TMB	TMB	1 vial, 12 ml	100 µl	RTU
Stop Solution STOPSOL	0.5 M H ₂ SO ₄	1 vial, 12 ml	100 µl	RTU

ADDITIONAL MATERIALS REQUIRED

As required for the selected MAIPA technique and protocol.

apDia offers following additional reagent & material kits:

Platelet-Antibody Screening Cells (set of 5 identical tubes)	Ref. 900001
Platelet-Antibody Identification Panel Cells Kit (set of 6 different cells)	Ref. 900002
Platelet-Antibody Control Plasma/Serum Kit (set of 4 controls)	Ref. 900003
Complete MAIPA Kit Consists of a combination of 5 kits: 900001, 900002, 900003, 900004 and 900005 (contains all cells, control plasma/serum, reagents and materials to perform a complete MAIPA test)	Ref. 900006

SAMPLE MATERIAL

1. Serum or plasma can be used for indirect MAIPA.
2. Platelets isolated from EDTA whole blood can be used for direct MAIPA.

USE AND STORAGE



All components of the MAIPA Reagents Kit and all components of the MAIPA ELISA Detection Kit may be stored at 2-8°C until the expiry date indicated on the label. Reagents should be used within two months after the first opening.

TMB must always be protected from light.
An environment temperature in the lab of 19-25 °C is advised.

PERFORMANCE CHARACTERISTICS

In a validation study in a French Reference Lab for Platelet Immunology 29 platelet-antibody positive samples were analyzed 3 times (triplicates) by the MAIPA technology using the apDia reagents (ref. 900001, 900002, 900003, 900004 and 900005). In this study a **diagnostic sensitivity** of 97.8 % was obtained (2/(29*3) tests were found negative).

In the same study using the apDia reagents described above, 326 true platelet-antibody negative samples were analyzed of which 325 were found negative resulting in a **specificity** of 99,7 %.

LIMITATIONS

MAIPA is considered as the gold standard method for platelet antibody detection and identification. False positive or false negative results may occur in case of bacterial or other contamination.

In case of spurious or even inconsistent results we recommend to have the sample examined by another laboratory specialized in platelet diagnostics or in a platelet reference laboratory.

MAIPA sensitivity and specificity is high but not 100%. Furthermore to obtain reliable test results it is necessary that the given protocol is strictly followed. The test is designed to detect IgG-type anti-platelet antibodies only.

The apDia platelet products (Ref. 900001 and Ref. 900002) are not useful for screening and identification of the HPA-15 system. This group is included for information purposes only. For HPA-15a and HPA-15b some specific platelets are required to identify the antibodies. Additionally, a specific monoclonal antibody is required.

BIBLIOGRAPHY

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PRODUCTS

MAIPA Reagents Kit Ref. 900004
(Monoclonal Antibodies, Cell Wash Buffer, Platelet Lysis Buffer and Microplate)

MAIPA ELISA Detection Kit Ref. 900005
(Coated Microplate, Antibody Conjugate, ELISA Wash Buffer, Chromogen and Stop Solution)



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